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EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/621,196	Applicant(s) SHACHAR, YEHOASHUA	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-43 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/17/08, 11/12/08, 11/13/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the RCE filed 9/10/2008. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/10/2008 has been entered.
2. Claim 39 is amended. **Claims 39-43 and 45-47** remain pending and under prosecution.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 9/17/2008, 11/12/2008, and 11/13/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 39, 42 and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) in view of Nowlin et al. (US 6,459,926) and Borst (WO 95/01757).

6. Note that Blume uses the calculations of Werp et al. (US 6,015,414) and incorporates Werp by reference (see Blume, paragraph bridging columns 6 and 7).

7. Blume discloses an apparatus for controlling movement of a tool to be inserted into the body of a patient, comprising: a controllable magnetic field source (12) having a first cluster of electromagnet poles (X+, Y- in figure 4) and a second cluster of electromagnet poles (X-, Y+), said first cluster of poles substantially opposed to said second cluster of poles; a tool (column 5, lines 18-21) having a distal end responsive to said magnetic field; one or more sensors (20) configured to sense a current position of said distal end; and a system controller (112) for controlling said magnetic field source to control a movement of said distal end according to a feedback calculation (see formulas in column 6 of Werp) wherein said system controller is configured to compute a position error comprising a difference (error/correction vectors of Werp) between a desired position of said distal end and said current position of said distal end. In regards to claim 42, the apparatus comprises an operator interface unit (column 8, lines 7-19).

8. Although Blume discloses a Virtual Tip control device (column 8, lines 7-19), Blume does not expressly disclose that the system controller computes an amount of tactile feedback according to the position error and does expressly disclose a Virtual Tip Calibration Fixture.

9. Nowlin teaches computing an amount of tactile feedback according to a position error (column 19, lines 23-67) so that the master and slave controllers are in

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corresponding positions. Furthermore, the feedback will tactilely notify a surgeon that the surgical tool has encountered resistance to movement in a desired direction (column 19, last paragraph). In regards to claim 45, Nowlin further teaches a Virtual Tip Calibration Fixture (200).

10. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the system controller of Blume to compute an amount of tactile feedback according to the position error such as when said position error exceeds a predetermined amount and to have used a calibration fixture as taught by Nowlin in order to ensure that the position of the Virtual Tip corresponds to the internal position of the tool and to notify a surgeon of resistance to movement in a particular direction.

11. Blume also does not expressly disclose a correction input to said desired position computed based on data from an auxiliary device that measures a position of a heart relative to a frame of reference, such that said system controller compensates for a dynamic position of a wall of a heart chamber such that said distal end moves substantially in unison with a natural motion of said wall.

12. Borst teaches a controller (8) for a robotic surgical system (figure 1), wherein a correction input is computed based on data from an auxiliary device (1, 2) that measures a position of a heart relative to a frame of reference, such that said system controller can compensate for a dynamic position of a wall of a heart chamber such that a distal end moves substantially in unison with a natural motion of said wall (paragraph bridging pages 22 and 23). The correction input compensates and corrects for heart motion to

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enable surgeries to be carried out on a beating heart without the need for extracorporeal circulation or cold cardioplegic cardiac arrest (page 14, lines 7-10).

13. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a correction input such that a tool distal end can move in unison with a wall of a heart chamber as taught by Borst in the apparatus of Blume as modified by Nowlin in order to allow surgeries to be carried out on a beating heart with minimal risk and operating time by eliminating the need for extracorporeal circulation or cold cardioplegic cardiac arrest.

14. In regards to the newly amended claim language, it is noted that Borst states, "It is preferred to partly immobilize the coronary artery segment" (page 20, lines 13-14). Borst merely states that the immobilization is preferred and not required to practice the invention. Therefore, the teaching of Borst is fully capable of working with the natural motion of a heart wall as claimed. Also, it is respectfully submitted that a partially immobilized coronary artery segment still exhibits natural motion to some degree.

15. **Claims 40 and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926) and Borst (WO 95/01757), as applied to claims 39, 42 and 45 above, and further in view of Solf et al. (US 6,587,709).

16. Blume as modified by Nowlin and Borst does not expressly disclose one or more piezoelectric rings.

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17. Solf teaches using piezoelectric rings (10a, 10b, 10c) with an ultrasound emitter (1) for the purpose of automatically tracking a catheter tip without manual displacement of an ultrasound transducer (abstract; column 2, lines 39-46).

18. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used piezoelectric rings as taught by Solf in the apparatus of Blume as modified by Nowlin and Borst in order to automatically and accurately track a catheter tip at all times.

19. **Claim 43** is rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926) and Borst (WO 95/01757), as applied to claims 39, 42 and 45 above, and further in view of Hastings (US 6,148,823).

20. Blume as modified by Nowlin and Borst does not expressly disclose that the first cluster of poles is connected to said second cluster of poles by a magnetic material.

21. Hastings teaches that magnetic poles can be connected by magnetic material for the purpose of providing a strong field for a given magnet cost (column 3, lines 39-42).

22. It would have been obvious to one having ordinary skill in the art at the time of invention to have connected the clusters of poles of Blume as modified by Nowlin and Borst with magnetic material as taught by Hastings in order to provide a stronger field for a given magnet.

23. **Claims 46 and 47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (US 6,014,580) as modified by Nowlin et al. (US 6,459,926) and Borst (WO

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95/01757), as applied to claims 39, 42 and 45 above, and further in view of Haynor et al. (US 6,129,668) and Tanabe et al. (US 5,550,469).

24. Blume further discloses a communication controller (54). However, Blume as modified by Nowlin and Borst does not expressly disclose one or more magnetic field sensors.

25. Haynor teaches one or more Hall-effect magnetic sensors to sense a position of a tool by sensing a magnetic field produced at the tool for the purpose of obviating the need to independently verify positioning with imaging equipment (column 2, lines 42-47).

26. It would have been obvious to one having ordinary skill in the art at the time of invention to have used one or more magnetic sensors as taught by Haynor in the apparatus of Blume as modified by Nowlin and Borst in order to determine the position of an indwelling tool without the need for imaging equipment.

27. Blume as modified by Nowlin, Borst and Haynor does not expressly disclose one or more temperature sensors.

28. Tanabe teaches a temperature-dependent variable resistor which is considered a temperature sensor for the purpose of compensating the temperature dependence of Hall-effect sensors (abstract). The temperature sensor is paired with magnetic sensors.

29. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have paired temperature sensors as taught by Tanabe with the Hall-effect sensors of Blume as modified by Nowlin, Borst and Haynor in order to compensate for the temperature dependence of Hall-effect sensors.

Response to Arguments

30. Applicant's arguments filed 9/10/2008 have been fully considered but they are not persuasive. Applicant argues, "In teaching separate control systems, Borst teaches away from the claimed providing a correction input to a system processor that computes tactile feedback. The system of Borst does not teach or render obvious a system where both tactile feedback and motion compensation is provided by a system controller that controls the claimed electromagnets to move a tool having a distal end responsive to magnetic fields. The system of Borst which provides separate control functions is thus inapplicable to the claimed system where only one control modality, the magnetic fields generated by the electromagnets, is available to provide force to move the tip."

31. In response, it is noted that the rejection relies on both Blume and Nowlin to teach a system controller that computes tactile feedback. The rejection then modifies Blume and Nowlin with the correction input taught by Borst to meet all limitations of claim 39. It is respectfully noted that claim 39 does not require that a correction input be provided to a system processor. The claims merely states, "a correction input to said desired position is computed." Borst clearly teaches computing a correction input to said desired position. In addition, a broadest, reasonable interpretation of a system controller does not require that the controller be a single component. Therefore, even though Borst may teach separate control functions, the separate control functions may be considered components of a multi-component system controller. In response to Applicant's argument that the separate control function are inapplicable to the claimed system of only one control modality, Borst teaches a combined motion resulting from the composite of the two control signals (page 24, lines 2-6). Since Borst teaches a composite of the two

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control signals, the teachings are fully applicable to the single magnetic control modality of Blume as modified by Nowlin and the claimed invention. One of ordinary skill in the art at the time of invention would have readily been able to apply the teachings of Borst to the apparatus of Blume as modified by Nowlin to obtain the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736